DP BARCODE No.: D351854 **REG. No.:** 5481-218 **PRODUCT NAME:** 1-Naphthalene Acetic Acid Sodium Salt

DATE: 08 / MAY / 2008

FEE

SUBJECT: **FEE.PRODUCT CHEMISTRY REVIEW OF TGAI/MP [X] EP [ ]**
DP BARCODE No.: D351854 **REG. No.:** 5481-218
PRODUCT NAME: 1-Naphthalene Acetic Acid Sodium Salt
COMPANY: AMVAC Chemical Corporation
PCC: 056007; **Decision No.:** 390094; **ACTION CODE:** R340
FOOD USE [X]
INTEGRATED FORMULATION: Yes [X] No [ ]

FROM: Shyam B. Mathur,
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

S Bmathur 5/8/07

TO: Rosemary Kearns / Tony Kish, RM 22
Fungicide Branch / RD (7505P)

INTRODUCTION

The registrant AMVAC has submitted an application to amend the registration of 1-Naphthalene acetic acid sodium salt (NAA Na salt) reflecting the addition of alternate manufacturing site in [redacted] The registrant has originally submitted a proposed alternate CSF (dated 02-22-08) to represent the alternate production site [redacted] The registrant has also submitted product chemistry data for the 830 series group A supporting the proposed alternate CSF with MRID Nos. 473545-01 through 473545-06. The reviewer on April 30, 2008 contacted the registrant (Mr. Jon C. Wood) and apprised him regarding the issues with the proposed alternate CSF (dated 02-22-08), presence of new impurities, the proposed product label and the group B product chemistry data. To resolve all the issues, Ms. Kaila Moran of AMVAC on May 7, 2008 sent the communication which included: request to change the originally submitted alternate CSF (dated 02-22-08) to proposed basic CSF (dated 05-05-08) and will replace the current basic CSF (dated 02-17-88), a revised & corrected product label (Ref. No. 218-200805055r2), a certified statement that the new impurities present are not considered to be of any toxicological significance and cited MRID No. 40523003 for group B (physical-chemical properties) data for the technical produced [redacted] TRB has been asked to determine whether the data submitted corresponding to 830 series group A support the proposed basic CSF (dated 05-05-08) and determine its acceptability.

SUMMARY OF FINDINGS

1. The nominal concentration of the active ingredient NAA sodium salt tgai/mup (96.22%) concurs with the revised product label claim nominal concentration of 96.22%. The current basic CSF (dated 02-17-88) has nominal concentration of 97% with a lower certified limit of 95% as the product label claim.

2. The proposed CSF for basic formulation (dated 05-05-08) is filled out correctly & completely. The nominal concentration of the AI (96.22%, dry) in the CSF concurs with the revised product label claim nominal concentration (96.22%). The values (% wt.) of the active ingredient and the impurities have been corrected to an anhydrous basis, because of the hygroscopic characteristics of the active ingredient. The proposed basic CSF is in compliance with PR Notice 91-2. The proposed certified limits for the AI are based on the minimum assay set for acceptance of this material and the maximum assay is set based on the reasonableness of making material having an assay greater than 99.5% without extraordinary procedures. The certified limits for the impurities are based on the variability of the observed values for precursors to these impurities in five batch analysis of the seven samples from the production of the AI and the averages of the various analyses.

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The product chemistry data submitted corresponding to guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.320 and 158.350 respectively [MRID No. 473545-01 & 473545-06].

3. The product chemistry data submitted corresponding to guideline reference 830.1600 (description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.325. The registrant has provided the MSDS's for all the chemicals used during the synthesis of NAA sodium salt tgai/mup produced by [redacted] [MRID No. 473545-02].

4. The product chemistry data submitted corresponding to guideline reference 830.1620 (description of production process) satisfy the data requirements for 40CFR§158.330. The production process for NAA sodium salt is a [redacted] The details of the manufacturing process have been provided. The processing conditions include good manufacturing practices during the production. The final product was checked for its specifications. The manufacturing process followed by producer [redacted] is not the same as the production process followed by the basic manufacturer [MRID No. 473545-03].

5. The product chemistry data submitted corresponding to guideline reference 830.1670 (discussion on the formation of impurities) satisfy the data requirements for 40CFR§158.340. During the production of NAA sodium salt the registrant discussed and reported the formation of [redacted] MRID No. 473545-04 and letter dated May 7, 2008].

6. The data submitted corresponding to guideline 830.1700 (preliminary analysis) satisfy the data requirements of 40CFR§158.170. [redacted] [MRID No. 473545-05].

8. The data submitted corresponding to guidelines 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.180. The analytical method described in item # 7 was used as enforcement analytical method [MRID No. 473545-05].

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CONCLUSIONS

TRB has evaluated the proposed basic formulation CSF and the supporting 830 series group A data and concluded that:

1. The product chemistry data submitted for 830 series group A which included the guidelines- 830.1550, 8301600, 830.1620, 830.1670, 830.1700, 830.1750 and 830.1800 are acceptable and support the proposed basic CSF (05-05-08).

2. The proposed basic CSF (dated 05-05-08) is acceptable and will supersede the current basic CSF (dated 02-17-88).

3. There are [redacted] new impurities identified in the technical produced [redacted] For the names of the impurities, please refer to Confidential Appendix on Page #6. The registrant has given a certified statement (dated May 7, 2008) that new impurities identified are not considered to be toxicological significant.

Manufacturing process information may be entitled to confidential treatment

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830.1550. Product Identity & composition: (MRID No.473545-01)

Chemical and Common names

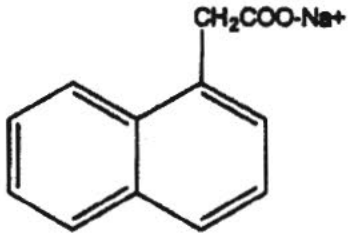
Product Name : 1-Naphthaleneacetic Acid, Sodium Salt

Chemical Name : Sodium 2-(1-Naphthyl)acetate

Common Name(s) : Sodium 2-(1-Naphthyl)acetate, Sodium salt of α-Naphthaleneacetic acid, NAA.Na, NAANa

CAS Number : 61-31-4

Structural Formula :



Empirical Formula : $C_{12}H_9O_2Na$

Molecular weight : 208.2

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Table 1. Group A data for 1-Naphthalene acetic acid sodium salt Technical				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	Basic CSF 05-05-08	A	473545-01
8301600	Description of materials used to produce the product	473545-02	A	For details see MRID number
830.1620	Description of production process	473545-03	A	For details see the MRID number
830.1670	Discussion of formation of impurities	473545-04	A	For details see MRID number & letter dated May 7, 2008
830.1700	Preliminary analysis	473545-05	A	For details MRID Number
830.1750	Certified limits	473545-06	A	For details see MRID number
830.1800	Enforcement analytical method	473545-05	A	For details see MRID number
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required				

Pages 6-17 Manufacturing process information may be entitled to confidential treatment